

# GIBSON DECLARATION- EXHIBIT 3

## **Vaccine Package Inserts: Post-Marketing Experience**

### **Blood and lymphatic system disorders**

- **Anemia, aplastic or hemolytic** (Pneumovax-23, ProQuad, Varivax)
- **Autoimmune hemolytic anemia** (Gardasil/Gardasil 9)
- **Epistaxis** [*nosebleed*] (ProQuad)
- **Extravasation blood** (ProQuad)
- **Hematochezia** [*bloody stools*] (ProQuad, Rotarix, Rota Teq)
- **Increased erythrocyte sedimentation rate** (Recombivax)
- **Leukocytosis** (MMR-II, Pneumovax-23)
- **Lymphadenitis** (Boostrix, Pneumovax-23, ProQuad)
- **Lymphadenopathy, including regional** [*enlarged lymph nodes*] (Boostrix, Daptacel, DT, Fluad, Fluarix, Flulaval, FluzoneQ and FluzoneHD, Gardasil/Gardasil 9, Infanrix, IPV, Kinrix, MMR-II, PedvaxHIB, Pneumovax-23, Prevnar-13, ProQuad, Tenivac)
- **Thrombocytopenia, including severe** [*low platelets*] (Afluria, Engerix-B, Fluad, FluzoneQ and FluzoneHD, Havrix, Infanrix, Kinrix, MMR-II, Pneumovax-23, ProQuad, Recombivax, Twinrix, Vaqta, Varivax)
- **Thrombocytopenic purpura, idiopathic (ITP)** (Gardasil/Gardasil 9, Rotarix, Twinrix, Varivax)

### **Cardiac disorders**

- **Cyanosis** [*bluish discoloration*] (Daptacel, Hiberix, Infanrix, Pediarix, Pentacel, Prevnar-13, Quadacel)
- **Myocarditis** [*inflammation of heart muscle*] (Adacel, Boostrix)
- **Palpitations** (Engerix-B, Twinrix)
- **Pericarditis** [*inflammation of pericardium*] (FluMist)
- **Tachycardia** [*abnormally high heart rate*] (Engerix-B, Fluarix, Recombivax, Twinrix)

### **Congenital**

- **Congenital anomaly** (Havrix)

### **Death**

- **Death** (Gardasil/Gardasil 9, MMR-II, Rotarix, Rota Teq)
- **SIDS** (Infanrix)

### **Ear and labyrinth disorders**

- **Ear pain** (Engerix-B, Infanrix, ProQuad, Twinrix)
- **Nerve deafness** (MMR-II, ProQuad)
- **Otitis media** (MMR-II)
- **Tinnitus** (Engerix-B, Recombivax, Twinrix)
- **Vertigo** (Engerix-B, Fluarix)

### **Eye disorders**

- **Conjunctivitis** (Engerix-B, Fluarix, MMR-II, Recombivax, Twinrix)
- **Eye irritation** (Fluarix, ProQuad)
- **Eye pain** (Fluarix, Flulaval)
- **Eye redness** (Fluarix)

- **Eye swelling** (Bexero, Fluarix)
- **Eyelid swelling** (Fluarix, ProQuad)
- **Keratitis** [*cornea inflammation*] (Engerix-B)
- **Ocular hyperemia** [*eye inflammation*] (FluzoneQ and FluzoneHD)
- **Ocular palsies** (MMR-II, ProQuad)
- **Optic neuritis/neuropathy, papillitis** (Engerix-B, FluzoneQ and FluzoneHD, MMR-II, ProQuad, Recombivax, Twinrix)
- **Photophobia** (Flulaval)
- **Retinitis, necrotizing retinitis** (MMR-II, ProQuad, Varivax)
- **Retrobulbar neuritis** (MMR-II, ProQuad)
- **Uveitis** [*eye inflammation*] (Recombivax)
- **Visual disturbances** (Engerix-B, Recombivax, Twinrix)

#### **Gastrointestinal disorders**

- **Abdominal pain or discomfort** (Fluarix, ProQuad)
- **Candidiasis** (ProQuad)
- **Constipation** (Recombivax)
- **Diarrhea** (Daptacel, FluMist, FluzoneHD, MMR-II, Pediarix, Pentacel)
- **Dyspepsia** (Engerix-B, Twinrix)
- **Dysphagia** [*swallowing difficulties*] (Flulaval)
- **Gastroenteritis** (Rotarix, Rota Teq)
- **Intussusception and recurrent intussusception (including fatal)** (Rotarix, Rota Teq) *((ACIP would allow exemption from further immunization with rotavirus vaccine only))*
- **Mouth ulcers** (ProQuad)
- **Nausea** (Daptacel, DT, Fluarix, FluMist, FluzoneHD, Gardasil/Gardasil 9, MMR-II, Pneumovax-23, TDVAX)
- **Pancreatitis** (Gardasil/Gardasil 9, MMR-II)
- **Swelling of the mouth, throat, and/or tongue** (Fluarix)
- **Vomiting** (Flulaval, FluMist, FluzoneQ and FluzoneHD, Gardasil/Gardasil 9, MMR-II, Pediarix, Pentacel, Pneumovax-23, Tenivac)

#### **General disorders and administration site conditions**

- **Abnormal gait** (Flulaval)
- **Apathy** (ProQuad)
- **Asthenia** [*fatigue, weakness*] (Fluarix, Flulaval, FluzoneQ and FluzoneHD, Gardasil/Gardasil 9, Infanrix, Pediarix, Tenivac)
- **Body aches** (Fluarix)
- **Chest pain** (Fluarix, Flulaval, FluzoneQ and FluzoneHD)
- **Chills** (Fluarix, FluzoneHD, Gardasil/Gardasil 9)
- **Decreased limb mobility** (Pneumovax-23)
- **Feeling hot** (Fluarix)
- **Fever** (MMR-II, Pneumovax-23)
- **Injected limb—extensive swelling** (ActHIB, Bexero, Hiberix)
- **Injection site abscess** (Adacel, Daptacel, Fluarix, Flulaval, PedvaxHIB, Pentacel, Quadracel)
- **Injection site bruising** (Adacel, Flulaval)
- **Injection site cellulitis** (Afluria, Daptacel, Fluad, Fluarix, Flulaval, Pediarix, Quadracel, Tenivac)
- **Injection site reactions: mass, pain, warmth** (Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, Havrix, Hiberix, Infanrix, IPV, Kinrix, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, TDVAX, Tenivac, Twinrix)

- **Injection site rash** (Daptacel, Flulaval, IPV, Prevnar-13)
- **Listlessness** (Quadracel)
- **Malaise** (Gardasil/Gardasil 9, MMR-II, Pneumovax-23, TDVAX, Twinrix)
- **Peripheral edema** (ActHIB, MMR-II, Pneumovax-23, ProQuad, TDVAX, Tenivac, Varivax)
- **Pyrexia** (TDVAX)
- **Swelling** (MMR-II, ProQuad)

#### **Hepatobiliary and liver disorders**

- **Elevation of liver enzymes** (Recombivax)
- **Hepatitis** (Havrix, Twinrix)
- **Jaundice** (Havrix, Twinrix)

#### **Immune system disorders**

- **Allergic reactions/hypersensitivity** (ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, Engerix-B, Fluarix, Flublok, FluMist, FluzoneQ and FluzoneHD, Hiberix, Infanrix, IPV, Kinrix, Pediarix, Pentacel, Quadracel, Recombivax, Tenivac, Trumenba, Twinrix)
- **Anaphylactic and anaphylactoid reactions, including shock** (ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, Engerix-B, Fluad, Fluarix, Flublok, Flucelvax, Flulaval, FluMist, FluzoneQ and FluzoneHD, Havrix, Hiberix, Infanrix, IPV, Kinrix, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, ProQuad, Quadracel, Recombivax, RotaTeq, Tenivac, Trumenba, Twinrix, Varivax) *(ACIP would only allow exemption from the triggering immunization only)*
- **Angioedema, angioneurotic edema** [swelling beneath skin] (ActHIB, Adacel, Boostrix, Daptacel, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, FluMist, FluzoneQ and FluzoneHD, Havrix, Hiberix, Infanrix, Kinrix, MMR-II, Pediarix, PedvaxHIB, Pneumovax-23, Prevnar-13, ProQuad, RotaTeq, Tenivac, Twinrix, Varivax)
- **Edema** (Adacel)
- **Hypotension** (Adacel)
- **Serum sickness** (Afluria, Engerix-B, Fluarix, Havrix, Pneumovax-23, Recombivax, Twinrix)

#### **Infections and infestations**

- **Atypical measles** (MMR-II, ProQuad)
- **Bronchitis** (Infanrix, ProQuad)
- **Cellulitis** (Daptacel, Infanrix, Pneumovax-23, ProQuad, TDVAX, Varivax)
- **Chills** (Havrix, Twinrix)
- **Early-onset Hib disease** (PedvaxHIB)
- **Herpes simplex** (ProQuad)
- **Herpes zoster** (Engerix-B, ProQuad, Recombivax, Twinrix, Varivax)
- **Infection** (ProQuad)
- **Influenza, influenza-like illness** (Afluria, Flulaval, Havrix, ProQuad)
- **Invasive Hib disease** (Pentacel)
- **Kawasaki disease** (Rotarix, RotaTeq)
- **Laryngitis** (Flulaval)
- **Measles** (ProQuad)
- **Measles-like rash** (MMR-II)
- **Meningitis, aseptic meningitis, eosinophilic meningitis** (Engerix-B, FluMist, MMR-II, Pentacel, ProQuad, Twinrix, Varivax)
- **Pharyngitis** (Fluarix, FluzoneHD, Varivax)
- **Pneumonia, pneumonitis** (MMR-II, ProQuad, Varivax)
- **Pulmonary congestion** (ProQuad)
- **Respiratory tract infection** (Infanrix, Pediarix, ProQuad)

- **Rhinitis** (Fluarix, Flulaval, FluzoneHD, Havrix, MMR-II, Pentacel, ProQuad)
- **Secondary bacterial infections of skin and soft tissue** (Varivax)
- **Sinusitis** (ProQuad)
- **Skin infection** (ProQuad)
- **Sore throat** (MMR-II, ProQuad)
- **Tonsillitis** (Fluarix)
- **Transmission of vaccine virus strains to non-vaccinated** (RotaTeq)
- **Varicella (vaccine strain)** (ProQuad, Varivax)
- **Varicella-like rash** (ProQuad)
- **Viral infection** (Pentacel)

#### **Investigations**

- **Abnormal liver function tests** (Engerix-B, Twinrix)
- **Increased serum C-reactive protein** (Pneumovax-23)

#### **Metabolic disorders**

- **Decreased appetite** (Pentacel)
- **Diabetes mellitus** (MMR-II)
- **Mitochondrial encephalomyopathy/Leigh syndrome exacerbation** [*neurometabolic disorder*] (FluMist)

#### **Musculoskeletal and connective tissue disorders**

- **Arthralgia** (Boostrix, Engerix-B, FluzoneHD, IPV, MMR-II, Pneumovax-23, ProQuad, Recombivax, TDVAX, Twinrix)
- **Arthritis** (Engerix-B, Flulaval, MMR-II, Pneumovax-23, ProQuad, Recombivax, Twinrix)
- **Back pain** (Boostrix)
- **Hypotonia** (Prenar-13)
- **Lupus-like syndrome** (Recombivax)
- **Muscle spasm** (Adacel)
- **Muscle weakness** (Engerix-B, Flud, Flulaval, Recombivax, Twinrix)
- **Musculoskeletal pain** (ProQuad)
- **Musculoskeletal stiffness** (Havrix)
- **Myalgia** (Boostrix, IPV, MMR-II, ProQuad, TDVAX, Tenivac)
- **Myositis** (Adacel)
- **Pain in extremities** (Fluarix, FluzoneQ and FluzoneHD, Pediarix, Recombivax, TDVAX, Tenivac)
- **Systemic lupus erythematosus (SLE)** (Recombivax)

#### **Nervous system disorders**

- **Acute disseminated encephalomyelitis (ADEM)** (MMR-II, ProQuad)
- **Ataxia** (MMR-II, ProQuad, Varivax)
- **Bulging fontanelle** (Pediarix)
- **Cerebellar ataxia** (Vaqta)
- **Convulsions/seizures** (ActHIB, Adacel, Afluria, Boostrix, Daptacel, DT, Flud, Fluarix, Flulaval, FluzoneQ and FluzoneHD, Havrix, Hiberix, IPV, Kinrix, MMR-II, Quadracel, Recombivax, TDVAX, Twinrix, Varivax)
- **Depressed level of consciousness** (Boostrix, Pediarix, Pentacel)
- **Dizziness** (Fluarix, Flulaval, FluzoneQ and FluzoneHD, Havrix, MMR-II, ProQuad, TDVAX, Tenivac, Varivax)

- **Encephalitis, vaccine-induced encephalitis** [*brain inflammation*] (Boostrix, Engerix-B, FluMist, MMR-II, Pediarix, Recombivax, Twinrix, Vaqta, Varivax)(*ACIP will only allow exemption from further vaccination with the triggering vaccine*)
- **Encephalomyelitis** [*inflammation of brain and spinal cord*] (Afluria, Fluad, Fluarix, FluzoneQ and FluzoneHD)
- **Encephalopathy** [*brain disease*] (Afluria, Engerix-B, Flulaval, Havrix, Infanrix, MMR-II, ProQuad, Twinrix)
- **Facial palsy, Bell's palsy** (Adacel, Boostrix, Engerix-B, Fluarix, FluMist, FluzoneQ and FluzoneHD, ProQuad, Recombivax, Twinrix, Varivax)
- **Facial (or cranial) nerve paralysis** (Flulaval)
- **Facial paresis** [*impaired movement*] (Fluarix)
- **Febrile convulsions/seizures** (Afluria, Daptacel, FluzoneQ and FluzoneHD, IPV, MMR-II, PedvaxHIB, Pneumovax-23, ProQuad, Quadracel, Recombivax)
- **Guillain-Barré syndrome** (Adacel, Afluria, Engerix-B, Fluad, Fluarix, Flulaval, FluMist, FluzoneQ and FluzoneHD, Havrix, MMR-II, PedvaxHIB, Pneumovax-23, ProQuad, Recombivax, Tenivac, Vaqta, Varivax)
- **Headache** (DT, Infanrix, IPV, MMR-II, ProQuad, TDVAX, Twinrix)
- **Hypoesthesia** [*decreased tactile sensitivity*] (Adacel, Engerix-B, Fluarix, Flulaval, Havrix, Recombivax, Twinrix)
- **Hypokinesia** [*loss of muscle movement*] (Flulaval)
- **Hypotonia** [*low muscle tone*] (Daptacel, Hiberix, Infanrix, Pediarix, Quadracel)
- **Hypotonic-hyporesponsive episode to immunization (HHE)** (Daptacel, Hiberix, Kinrix, Pediarix, Pentacel, Quadracel)
- **Lethargy** (Pediarix)
- **Limb paralysis** (Flulaval)
- **Measles inclusion body encephalitis (MIBE)** (MMR-II, ProQuad)
- **Migraine** (Engerix-B, Recombivax)
- **Multiple sclerosis (or MS exacerbation)** (Engerix-B, Havrix, Recombivax, Twinrix)
- **Myelitis** [*spinal cord disease*] (Adacel, Fluarix, FluzoneQ and FluzoneHD, Havrix, Recombivax, Twinrix)
- **Neuralgia** [*nerve pain*] (Afluria, Fluad)
- **Neuritis, including brachial, polyneuritis** [*nerve inflammation*] (Adacel, Afluria, Engerix-B, Fluad, Fluarix, FluzoneQ and FluzoneHD, MMR-II, Twinrix)
- **Neuropathy, polyneuropathy** [*nerve damage*] (Afluria, Engerix-B, Fluarix, Havrix, MMR-II, ProQuad, Recombivax, Twinrix)
- **Paralysis** (Engerix-B, Twinrix)
- **Paresis** (Engerix-B, Twinrix)
- **Paresthesia** [*abnormal skin sensations*] (Adacel, Afluria, Boostrix, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, FluzoneQ and FluzoneHD, Havrix, IPV, MMR-II, Pneumovax-23, ProQuad, Tenivac, Varivax)
- **Partial seizures, seizures** (Daptacel, Engerix-B, ProQuad)
- **Presyncope** [*feeling faint*] (Fluad, Flucelvax)
- **Radiculopathy** [*"pinched nerve" in spine*] (Pneumovax-23, Recombivax)
- **Somnolence** (Daptacel, DT, Flulaval, Havrix, Hiberix, IPV, Pediarix, Pentacel, Quadracel, Recombivax)
- **Subacute sclerosing panencephalitis (SSPE)** (MMR-II, ProQuad)
- **Syncope, vasovagal syncope** [*fainting*] (Adacel, Bexero, Boostrix, Daptacel, DT, Engerix-B, Fluad, Fluarix, Flucelvax, Flulaval, FluzoneQ and FluzoneHD, Havrix, Hiberix, Infanrix, Kinrix, MMR-II, Pediarix, ProQuad, Recombivax, Tenivac, Trumenba)
- **Transverse myelitis** [*spinal cord demyelination*] (Afluria, Engerix-B, FluzoneQ and FluzoneHD, MMR-II, ProQuad, Recombivax, Twinrix, Varivax)
- **Tremors** (Flulaval, ProQuad)

#### Psychiatric disorders

- **Agitation** (IPV, ProQuad, Recombivax)
- **Crying/unusual crying** (Pediarix)

- **Hypersomnia** (ProQuad)
- **Insomnia** (Flulaval, Pediarix)
- **Irritability** (MMR-II, Recombivax)
- **Nervousness** (Pediarix, ProQuad)
- **Restlessness** (Pediarix)
- **Screaming** (Daptacel, Pediarix, Pentacel, Quadracel)

#### **Respiratory, thoracic, and mediastinal disorders**

- **Apnea** (Engerix-B, Hiberix, Infanrix, Kinrix, Pediarix, Pentacel, Prevnar-13)
- **Asthma, asthma-like symptoms** (Engerix-B, Fluarix, Twinrix)
- **Bronchospasm** (Engerix-B, Fluarix, Flulaval, MMR-II, ProQuad, Recombivax, Tenivac, Twinrix)
- **Cough** (Fluarix, FluzoneQ and FluzoneHD, Infanrix, MMR-II, Pediarix, Pentacel)
- **Dyspnea** [*shortness of breath*] (Fluarix, Flulaval, FluzoneQ and FluzoneHD, Havrix, Pediarix, Quadracel, Twinrix)
- **Dysphonia** [*vocal abnormalities*] (Flulaval)
- **Epistaxis** [*nosebleed*] (FluMist)
- **Oropharyngeal pain** (FluzoneQ)
- **Respiratory distress** (Fluarix)
- **Rhinorrhea** [*runny nose*] (FluzoneQ)
- **Stridor** [*high-pitched wheezing*] (Fluarix)
- **Throat tightness** (Flulaval, FluzoneQ and FluzoneHD)
- **Wheezing** (FluzoneQ and FluzoneHD, ProQuad)

#### **Skin and subcutaneous tissue disorders**

- **Acute hemorrhagic edema of infancy** (MMR-II, ProQuad)
- **Alopecia** [*hair loss*] (Engerix-B, Recombivax, Twinrix)
- **Ecchymoses** [*subcutaneous bleeding*] (Engerix-B, Recombivax, Twinrix)
- **Eczema** (Engerix-B, Recombivax, Twinrix)
- **Erythema** [*skin redness*] (Fluarix, Infanrix, MMR-II, Pediarix, Pentacel, TDVAX)
- **Erythema multiforme** (Engerix-B, Fluad, Fluarix, Havrix, MMR-II, Pneumovax-23, ProQuad, Prevnar-13, Recombivax, Twinrix, Varivax)
- **Erythema nodosum** (Engerix-B, Recombivax, Twinrix)
- **Exanthem** [*widespread rash*] (Boostrix)
- **Facial swelling/edema** (Daptacel, Fluarix, MMR-II, ProQuad, Varivax)
- **Hyperhidrosis** [*abnormal sweating*] (Flulaval, Havrix, Twinrix)
- **Impetigo** (ProQuad, Varivax)
- **Lichen planus** [*inflammatory skin rash*] (Engerix-B, Twinrix)
- **Panniculitis** [*disease of fatty layer of skin*] (MMR-II, ProQuad)
- **Parotitis** [*inflammation of salivary glands*] (MMR-II, ProQuad)
- **Pruritus** [*itchy skin*] (ActHIB, Adacel, Afluria, Boostrix, Daptacel, Fluad, Fluarix, Flucelvax, Flulaval, FluzoneQ and FluzoneHD, Infanrix, Kinrix, MMR-II, Prevnar-13, ProQuad, TDVAX, Tenivac)
- **Purpura** [*red/purple spots*] (Engerix-B, MMR-II, ProQuad)
- **Rash** (ActHIB, Adacel, Afluria, Bexero, Boostrix, Daptacel, DT, Fluad, Fluarix, Flucelvax, Flulaval, FluMist, FluzoneQ, Hiberix, Infanrix, IPV, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, Quadracel, TDVAX, Tenivac)
- **Skin discoloration** (Pentacel)
- **Skin induration** (MMR-II, ProQuad)
- **Stevens-Johnson syndrome** [*severe skin reaction*] (Engerix-B, Fluarix, FluzoneQ and FluzoneHD, MMR-II, ProQuad, Recombivax, Varivax)

- **Urticaria** [*hives*] (ActHIB, Adacel, Afluria, Boostrix, DT, Engerix-B, Flud, Fluarix, Flucelvax, Flulaval, FluMist, FluzoneQ and FluzoneHD, Hiberix, Infanrix, IPV, Kinrix, MMR-II, Pediarix, Pentacel, Pneumovax-23, Prevnar-13, Quadracel, Recombivax, Rota Teq, Tenivac, Twinrix)
- **Vesiculation** (MMR-II)

#### **Vascular disorders**

- **Cerebrovascular accident** (ProQuad, Varivax)
- **Flushing** (Flulaval, FluzoneQ and FluzoneHD)
- **Henoch-Schönlein purpura** [*blood vessel inflammation*] (Boostrix, Fluarix, MMR-II, ProQuad, Varivax)
- **Pallor** (DT, Flulaval, Hiberix, Pediarix, Pentacel, Prevnar-13, Quadracel)
- **Petechiae** [*bleeding capillaries*] (Pediarix, Recombivax)
- **Polyarteritis nodosa** [*inflamed/damaged arteries*] (Recombivax)
- **Renal vasculitis** (Afluria, Flud)
- **Vasculitis** [*blood vessel inflammation*] (Afluria, Engerix-B, Flud, Fluarix, FluzoneQ and FluzoneHD, Havrix, MMR-II, Recombivax, Twinrix)

#### **Urogenital disorders**

- **Epididymitis** [*testicular inflammation*] (MMR-II, ProQuad)
- **Orchitis** [*inflammation of the testes*] (MMR-II, ProQuad)